

## **REMARKS/ARGUMENTS**

The rejections presented in the Office Action dated February 25, 2011 (hereinafter Office Action) have been considered. Claims 25, 35, 49-53, 55-62, 64 and 65 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claim 53 is rejected based on 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicant has amended claim 53 to obviate this rejection.

Claims 25, 35, 49-53, 55, 57, 59-62 and 64 are rejected based on 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,496,361 to Moberg et al. (hereinafter “Moberg”) in view of U.S. Patent No. 6,643,548 to Mai et al. (hereinafter “Mai”). Claims 56, 58 and 65 are rejected based on 35 U.S.C. § 103(a) as allegedly being unpatentable over Moberg and Mai, as applied to claims 25 and 35, and further in view of U.S. Patent No. 7,035,684 to Lee (hereinafter “Lee”).

Applicant appreciates the Examiner’s comments in the Response to Arguments beginning on page 7 of the Office Action regarding Applicant’s arguments filed 12/10/2010. Notwithstanding Applicant’s arguments to the contrary, the Examiner maintains that the combination of Moberg and Mai (and Lee for certain claims) render obvious Applicant’s claimed subject matter because Mai’s windowing technique (1) purportedly meets the claimed windowing technique and (2) purportedly can be implemented during tachyarrhythmias. Without acquiescing to the Examiner’s contention that Mai’s windowing technique meets the claimed windowing technique, Applicant respectfully asserts that the characterization of Mai’s windowing technique is erroneous, at least for the reason that Mai expressly teaches that its windowing technique is not used for unstable patient heart rates, such as tachyarrhythmia.

In its prior response, Applicant argued that:

Moreover, Mai teaches that its time intervals are determined when the patient’s rhythm is stable, such as when the patient is at rest. See, e.g., column 2, lines 43-46. Further, Mai teaches use of its time intervals for evaluating the progression of a patient’s heart failure status, and is silent on cardiac tachyarrhythmia of the patient.

The proposed modification of Moberg to incorporate Mai's technique of determining time intervals between a heart sound and a morphological feature of a cardiac cycle when the patient's rhythm is stable teaches away from Applicant's presently claimed features of using a correlation window to correlate heart sounds with cardiac cycle features to discriminate between normal cardiac function and cardiac tachyarrhythmia. One of ordinary skill in the art would immediately appreciate that Mai's time interval determination technique which requires a stable cardiac rhythm would be inapplicable where elevated and unstable cardiac rhythms are to be discriminated.

Because Mai is solely relied upon as teaching these features of Applicant's claims 54 and 63 and fails to do so, and because Mai (alone or in combination with Moberg) teaches away from the claimed invention for reasons discussed hereinabove, the rejection of claims 54 and 63 is improper and withdrawal of the rejection is necessitated.

On page 8 of the Response to Arguments, the Examiner contends that determining heart rate for stability in Mai is "optional," and that "it does not appear that a faster heart rate (tachyarrhythmia) would affect the operation of Mai's windowing algorithm to render it inoperable . . .". The Examiner contends that the "optional" heart rate stability determination represents only one of other alternatives described in Mai, and that "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed . . . *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004)."

Respectfully, Mai clearly teaches that its windowing technique is implemented only when heart rate is stable. Mai does not teach other alternatives that would circumvent its check on heart rate stability and still allow its windowing technique to be implemented for unstable heart rates. This is made clear in the textual and pictorial teachings of Mai, examples of which are provided below (emphasis added):

The time intervals and/or amplitudes are preferably determined for each cardiac cycle occurring over a time period, once each day, when the rhythm is being stable such as when the patient is at rest. The time intervals and/or amplitudes are then preferably averaged and the average time intervals stored in memory for later retrieval. [Column 2, lines 43-48]

An increase in either time interval, over time, may be indicative of a progression in the heart disease. Conversely, a decrease in the time intervals may be indicative of a regression in the heart disease. To assure consistent data collection, the time intervals are preferably determined from heart activity while the patient is at rest and the cardiac signals are stable. [Column 2, lines 49-56]

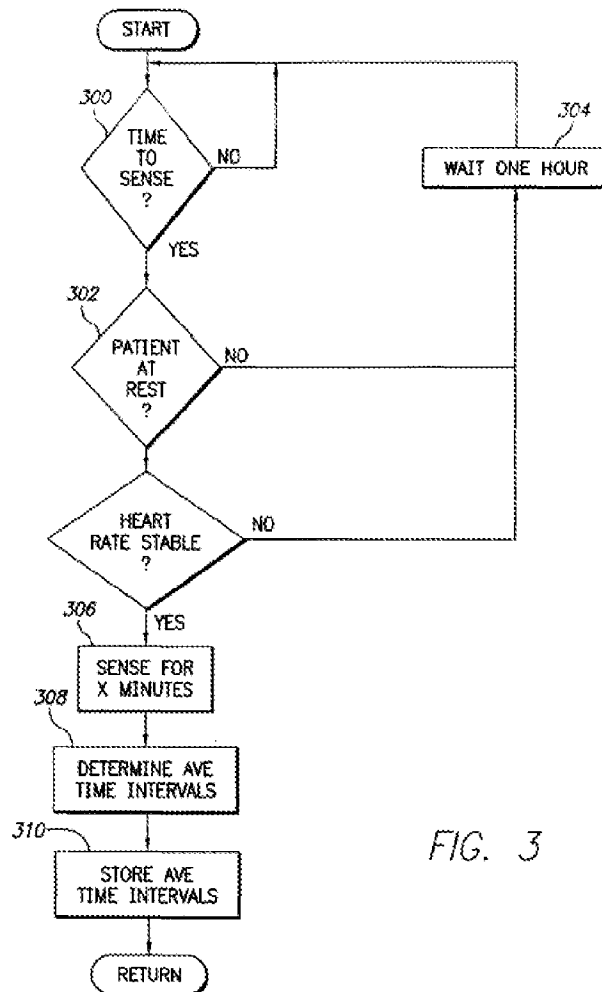


FIG. 3

The overall process illustrated in FIG. 3 initiates with decision block **300** wherein the processor **60** determines if it is time to sense electrogram and heart sound signals to initiate a monitoring period. If it is time to initiate such a monitoring period, the process advances to decision block 302 wherein the processor determines if the patient is at rest. As previously mentioned, the processor may determine if the patient is at rest by noting if the activity and activity variance of the patient is low. Also as previously mentioned, the activity and activity variance may be determined as fully

described in U.S. Pat. No. 5,476,483 which is incorporated herein by reference in its entirety. [Column 8, line 66 – Column 9, line 10]

Once the patient is detected to be at rest, the process (optionally) advances to block **305** where the processor determines whether the heart rate is stable, for example, by determining if the averaged heart rate is lower than a preset threshold, such as 80 bpm. [Column 9, lines 16-24]

If it is *not stable*, the process then advances to block **304** wherein the processor will wait for a fixed period of time, such as one hour. Following the fixed period of time, the process then returns to decision block **300**. [Column 9, lines 20-25]

If the patient's heart *is stable*, then the process then advances to activity block **306** wherein the electrogram and heart sound signals are sensed for a fixed period of time as, for example, on the order of one minute. Once the electrogram signal and heart sound signal have been sensed for the fixed period of time, the process then advances to activity block **308** wherein the R to S1 and S1 to S2 time intervals are determined for each cardiac cycle occurring during the monitoring period and then averaged. [Column 9, lines 26-34]

When activity block **308** is completed, the process then advances to activity block **310** wherein the average R to S1 time interval and the average S1 to S2 time interval are stored in memory for later telemetric retrieval. The process then returns. [Column 9, lines 35-38]

Figure 3 of Mai and accompanying text unambiguously shows that Mai's windowing algorithm is implemented only when the patient's heart rate is stable, such as at an average heart rate lower than 80 bpm, per Mai's specific example quoted above. One skilled in the art would readily know that an average heart rate lower than 80 bpm (or other heart rate indicative of patient resting) is far lower than a heart rate indicative of tachyarrhythmia.

Mai teaches that if patient heart rate is unstable, as tested at Block 305 (reference number 305 is missing, but is labeled "Heart Rate Stable?" in Figure 3), processing proceeds to Block 304, where the processor waits for one hour before returning to the logic at Block 300. If, after the one hour wait time, the heart rate is still unstable, processing again proceeds to Block 304, where the processor waits for one hour before returning to the logic at Block 300. This logic loop is repeated until the patient's heart rate becomes stable (i.e., the patient's bpm is under a predetermined limit, such as 80 bpm) or the logic of Figure 3 is exited by the processor. Nowhere in Mai is there a description that the logic loop of Blocks 300→305→304→300 is

bypassed if the heart rate is unstable. Accordingly, Mai's windowing algorithm is never implemented if the patient's heart rate is unstable.

In the above-quoted excerpts, Mai teaches that a patient's "activity and activity variance may be determined as fully described in U.S. Pat. No. 5,476,483 to Bornzin et al." (hereinafter "Bornzin"). Significantly, Bornzin discloses "activity and activity variance" determinations made by a rate-responsive cardiac pacemaker (*see, e.g.*, Abstract). Bornzin does not teach or even mention tachycardia, and clearly fails to teach activity and activity variance determinations for patient tachyarrhythmia.

Applicant respectfully submits that one skilled in the art would disagree with the Examiner's contention that Mai's windowing technique can be used for unstable patient heart rates, such as tachyarrhythmia. The Examiner's contention is mere unsupported speculation that is contradicted by the express teachings of Mai and Bornzin.

The Examiner's contention that Mai's "optional" heart rate stability determination represents only one of other alternatives described in Mai is also unsupported by the teachings of Mai and is erroneous. Mai fails to describe any such alternative that would allow for violation of its check on heart rate stability at Block 305 in Figure 3. Mai's use of the parenthetical comment "(optional)" in Column 9, line 17 does not vitiate the fact that Mai fails to describe an alternative that would render Applicant's "teaching away" arguments inapplicable in view of *In re Fulton*.

"When references teach away from the claimed combination, it is improper to combine them in an obviousness rejection." *Ex Parte Dirk Rode, Thomas Helmenkamp, and Fred Riechert*, 2008 WL 4898228 (Bd. Pat. App. & Interf. 2008) (citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983). "[I]n the case where a reference specifically criticizes an alternative, the reference teaches away from that alternative." *Id.* (citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). Applicant respectfully asserts that Mai expressly discourages "the solution claimed" in Applicant's pending claims. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Because Mai expressly requires testing of heart rate stability at Block 305 shown in Figure 3 before its windowing algorithm can be implemented, and because Mai fails to provide any alternative to that would allow for implementation of its windowing algorithm upon failure of the heart rate stability test at Block 305, Mai teaches away from Applicant's claimed correlation window processes for discriminating between normal cardiac function and cardiac tachyarrhythmia.

Because Mai is solely relied upon as teaching various correlation window processing features of Applicant's claims and Mai fails to do so, and because Mai (alone or in combination with Moberg and Lee) teaches away from the claimed invention for reasons discussed hereinabove, the rejection of Applicant's claims is improper and withdrawal of the rejection is necessitated.

To the extent the current response has not responded to any characterization in the Office Action of the asserted art or of the claimed subject matter, or to any application in the Office Action of the asserted art to any claimed subject matter, any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Office Action's characterizations, or any other assertions or statements beyond that provided above is unnecessary in view of the present response. The right to address in detail any such assertions or statements in the future is reserved.

Applicant respectfully submits that the claims are in condition for allowance, timely notification of which is kindly requested. Authorization is given to charge Deposit Account No. 50-3581 (GUID.609PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,  
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